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| SERIAL NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NO. |
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| 06/346,319 | 02/05/82 | MEYER H | BAYER3611.1 |

SPRUNG, HORN, KRAMER & WOODS
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| EXAMINER | |
|-------------|--------------|
| FRIEDMAN, S | |
| ART UNIT | PAPER NUMBER |
| 125 | 4 |

MAILED

DATE MAILED: ~~SEP 17 1982~~

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

SEP 17 1982

GROUP 120

☒ This application has been examined. ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892 2. ☐ Notice of Informal Patent Drawing, PTO-948
3. ☐ Notice of References Cited by Applicant, PTO-1449 4. ☐ Notice of Informal Patent Application, Form PTO-152

Part II SUMMARY OF ACTION

1. ☒ Claims 1-4 + 6-10 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims all are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ The formal drawings filed on _____ are acceptable.
8. ☐ The drawing correction request filed on _____ has been ☐ approved. ☐ disapproved.
9. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has
☐ been received. ☐ not been received. ☐ been filed in parent application, serial no. _____
filed on _____
10. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
11. ☐ Other

Art Unit 125

All claims are rejected as being obvious (35 USC 103) over Chem. Abst., which teaches the instant compound as old and with uses (therapeutic), which would clearly have value for the claimed use. The formulations are, of course, prima facie obvious, reading on obvious formulations of old therapeutics.

The compounds do not become new and patentable merely because they are combined with a pharmaceutical carrier. Ex parte Billman, 71 USPQ 253, In re Riden et al., 50 CCPA 1411; 318 F. 2d 760; 1963 CD 794; 796 OG 863; 138USPQ 112, In re Pieroh et al., 50 CCPA 1471; 319 F 2d 248; 797 OG 6; 138 USPQ 238, In re Rosicky, 47 CCPA 859; 276 R2d 656; 1960 CD 197; 755 OG 929; 125 USPQ 341. The dosages recited in the claims do not constitute a patentable distinction. The dosage would vary considerably with the animal treated and it would be within the ordinary skill of the art to determine suitable dosages. The dosages are not deemed to be critical. The claims refer to "an amount effective for treatment of cerebral disorders"; "0.1 to 90%"; "0.5 to 90%"; "0.0001 to 0.5mg per Kg...etc"; "0.001 to 1 mg per Kg ...etc."; and "0.01 to 0.5 mg per Kg ...etc". Such broad amounts can hardly be considered critical nor can the functionally defined amount. Further such amounts when incorporated in formulation claims are not-limited to the use therein. As for the method of use claims, it

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is quite clear that coronary dilation and lowering of blood pressure would have value for the claimed use. The Kazada Declaration of the parent (Paper No. 9) merely established an ED_{50} value and compared same with an adjacent homolog. Such is interesting, but hardly relates to the instant situation as the rejection is not over a homolog. Further, the Declaration does not establish a critical^{ity} of claimed amounts.

SFriedman:srb

A/C 703

557-2575

9/7/82


Stanley J. Friedman
Primary Examiner
Group Art Unit 125